DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
M2880

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

August 23, 1999

Ref: 99-DAL-WL-26

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. James W. Herring, Owner
GemKen Enterprises
950 East Bitters Road, Suite 611
San Antonio, Texas 78216

Dear Mr. Herring:

This letter is in reference to the marketing and distribution of "Pelocell Shampoo" by your firm. During an inspection of your facility located at the above address on July 7, 1999, our investigator determined that you are an own-label distributor and [redacted] is the contract manufacturer of this product.

According to the label, "Pelocell Shampoo" contains saw palmetto, tea tree oil, panthenol, vitamin B6, and other ingredients. The labeling, including promotional materials on your Internet web site, contain statements such as: "Natures Stimulant for Thinning Hair," "Formulated to stop hair loss and promote new hair growth," "Pelocell has ingredients that work to stimulate the follicle and root and provide nourishment which helps to strengthen and save your hair," and "Once Pelocell stops or slows your hair loss, you can expect to see new hair growth."

Based on the intended uses described above, "Pelocell Shampoo" is a drug (section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)) and is subject to the final rule covering Hair Grower and Hair Loss Prevention Drug Products for Over-the-Counter Human Use Title 21, Code of Federal Regulations (21 CFR), Part 310.527. Under that rule, no ingredients are generally recognized as safe and effective to grow hair or prevent hair loss. Therefore, "Pelocell Shampoo" is a "new drug" (section 201(p) of the Act). A "new drug" may not be marketed in the United States without an approved new drug application (NDA) (section 505(a) of the Act). In addition, this product is also misbranded (section 502(f)(1) of the Act), because it does not bear adequate directions for use for the indications noted above.

"Pelocell" is also misbranded (section 502(o) of the Act) because it has not been drug listed as required (section 510(j) of the Act) and is further misbranded (section 502(a) of the Act) because the label fails to identify GemKen Enterprises as the distributor, rather than the manufacturer, of the product (21 CFR 201.1(h)).

The violations cited in this letter are not intended to be a statement of all the violations that may exist for products marketed by your firm. It is your responsibility to assure that all your products are in compliance with federal laws and regulations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering contract awards. Failure to promptly correct these violations may result in regulatory action without further notice. Such actions include a seizure and/or an injunction.

Within fifteen (15) working days of your receipt of this letter, please notify this office in writing of the specific steps you will take to correct the noted violations. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed. Copies of revised labels and promotional materials should be included with your response.

Your reply should be sent to the Food and Drug Administration at the above letterhead address to the attention of Reynaldo R. Rodriguez, Jr., Compliance Officer.

Sincerely,

for

Joseph B. Baca
District Director

cc: [redacted] President